

DUANE READE HOT AND COLD ROLL-ON- methyl salicylate and menthol gel

Duane Reade

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredients Purpose

Methyl Salicylate 29%Topical Analgesic

Menthol 7.6%Topical Analgesic

Uses

temporarily relieves the minor pains associated with:

- arthritis
- cramps
- bruises
- sprains
- backache

Warnings

For external use only

When using this product

- use only as directed
- avoid contact with eyes or mucous membranes
- do not bandage tightly or use with a heating pad
- do not apply to wounds or damaged skin

Stop use and ask a doctor if

- condition worsens
- redness is present
- irritation develops
- symptoms persist for more than 7 days or clear up and occur again within a few days

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions adults and children over 12 years :

- apply generously to affected area
- massage into painful area until thoroughly absorbed into skin

- repeat as necessary, but no more than 4 times daily

children under 12 years: ask a doctor

Inactive ingredients


purified water/aqua/eau, sd alcohol 40-b,
propylene glycol, isopropyl myristate,
glycerin, triethanolamine, carbomer

Allergy alert:


If prone to allergic reaction from aspirin or salicylates, consult a doctor before use.

Placeholder Text

NDC# 24488-023-03

UNIQUELY NY  SINCE 1960

hot and cold
roll-on



extra strength

relief of minor muscle
& joint aches due to:
sprains, bruises,
backache, and arthritis


net wt 2.5 OZ (74 mL)

Drug Facts (continue)

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions adults and children over 12 years: ■ apply generously to affected area ■ massage into painful area until thoroughly absorbed into skin ■ repeat as necessary, but no more than 4 times daily children under 12 years: ask a doctor

Inactive ingredients purified water/aqua/eau, sd alcohol 40-b, methyl salicylate, menthol, propylene glycol, isopropyl myristate, glycerin, triethanolamine, carbomer

Item# 51068-2.5

 3 11917 12922 8

Drug Facts

Active ingredients Purpose
Methyl Salicylate 29% Topical Analgesic
Menthol 7.6% Topical Analgesic

Uses temporarily relieves the minor pains associated with: ■ arthritis ■ cramps ■ bruises ■ sprains ■ backache

Warnings For external use only

Allergy alert: if prone to allergic reaction from aspirin or salicylates, consult a doctor before use.

When using this product ■ use only as directed ■ avoid contact with eyes or mucous membranes ■ do not bandage tightly or use with a heating pad ■ do not apply to wounds or damaged skin

Stop use and ask a doctor if ■ condition worsens ■ redness is present ■ irritation develops ■ symptoms persist for more than 7 days or clear up and occur again within a few days

If pregnant or breast-feeding, ask a health professional before use. ▶

100% GUARANTEED DISTRIBUTED BY DUANE READE / (866) 375-6925
440 NINTH AVE., NY, NY 10001 / duanereade.com © 2011 Duane Reade

DR_hot and cold roll-on_label_3x4.75_rev 6

DUANE READE HOT AND COLD ROLL-ON

methyl salicylate and menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24488-023
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (METHYL SALICYLATE - UNII:LAV5U5022Y)	METHYL SALICYLATE	21.46 mL in 74 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5.62 mL in 74 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER INTERPOLYMER TYPE A (55000 MPA.S) (UNII: 59TL3WG5CO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24488-023-03	74 mL in 1 BOTTLE, WITH APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/28/2011	

Labeler - Duane Reade (961956229)**Registrant** - Creations Garden Natural Products Inc. (961956229)**Establishment**

Name	Address	ID/FEI	Business Operations
Creations Garden Natural Products Inc.		961956229	manufacture